The FDA has eased the way for pharmaceutical manufacturers to automate processing lines with safe, fast, and adaptable vacuum transfer equipment. This article discusses ways that vacuum systems can improve pharmaceutical manufacturing processes.

Recent FDA regulations and guidances have simplified the notification procedure pharmaceutical companies must follow when making certain changes to equipment, technology, and processes. The agency now considers adopting material handling equipment such as a pneumatic conveyor a level-one change, which the company may document in an annual report rather than in a time-consuming supplement.

Several FDA documents indicate that automated material transfer is preferred over manual transfer for pharmaceutical processes. Appendix A in the FDA’s “CMC Postapproval Manufacturing Changes to be Documented in Annual Reports” states that a “decrease in the number of open handling steps or manual operation procedures” has “minimal potential to have an adverse effect on product quality.”

Similarly, “Immediate Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation” states that “change from non-automated or non-mechanical equipment to automated or mechanical equipment to move ingredients” is “unlikely to have any detectable impact on formulation quality and performance.”

As a result of this FDA guidance, pharmaceutical companies are increasingly incorporating vacuum transfer equipment into their manufacturing processes. Compared to manual transport and loading, a vacuum conveyor can reduce safety, sanitation, and environmental hazards; increase processing-line speed; and streamline production.

To clarify how vacuum transfer equipment, which operates in semi-continuous and continuous modes, fits into pharmaceutical manufacturing, which is typically a batch process, the FDA also changed the definition of “batch” in CFR Title 21 210.3(b)(2) to read:

“Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.”

Under this definition, the term “batch” is no longer tied to the operating mode; a batch process can be continuous or semi-continuous depending on the level of automation.

While it’s possible to completely automate a pharmaceutical manufacturing process, this requires a costly system overhaul and extended production downtime. Vacuum transfer systems, on the other hand, easily integrate into existing processes; can be routed between floors, through partitions, and around machinery; and can be easily rerouted to accommodate process modifications. These systems are cleaner, safer, more accurate, and more cost effective than manual material handling methods but more practical and affordable than completely automated processes.

Vacuum transfer system basics

A basic vacuum transfer system consists of a vacuum producer (a vacuum pump or blower), a high-efficiency filter, a
conveying line (piping or hose), and a collection bin or hopper. In operation, the vacuum producer generates an airstream that draws the material into the piping and carries it from one plant location to another or between different processing machines, such as mixers and reactors, hammer mills, feeders, tablet presses, gelcap machines, and packaging equipment. When the material reaches its destination, it drops out of the airstream and collects in the bin or hopper. The high-efficiency filter separates any remaining airborne particles from the airstream, preventing them from reaching the vacuum producer and escaping into the workspace.

The system can transfer the material using either dilute-phase or dense-phase conveying depending on the application. In dilute-phase conveying, the material is entrained in the airstream and the air-to-material ratio is high. In dense-phase conveying, the material moves in slugs within the piping. Since the material moves slower in dense phase than in dilute phase, dense-phase conveying is an excellent choice for friable materials or powder blends.

Because each application is unique, pneumatic conveying system manufacturers generally have test labs and fabrication capabilities and will customize each vacuum transfer system to the customer's needs using standard components.

**Benefits of vacuum transfer systems**

The benefits of vacuum transfer systems over manual material transfer include improved dust containment, ergonomics, segregation prevention, and throughput as well as reduced downtime, material spilling and mishandling, and environmental impact.

**Dust containment.** Manual material dumping generates fugitive dust, which can remain suspended in the air for days or weeks, endangering worker health, settling on equipment and surfaces, and posing cross-contamination risks and explosion hazards. A vacuum pneumatic conveying system avoids these hazards by containing the dust and preventing it from escaping into the workspace. For highly hazardous materials, the system can include additional safety features, such as HEPA filtration, to ensure the safety of the exhaust airstream.

**Ergonomics.** Using a vacuum conveying system to automatically load or refill feeders, hammer mills, mixers, reactors, screeners, or other processing equipment can also help eliminate potential ergonomic issues associated with manual material transfer, such as repetitive-motion injuries and falls. Depending on the level of automation, a company paying $250,000 per year in disability payments for injuries related to manual material transfer might achieve almost instant return on investment by adding vacuum transfer equipment. Vacuum transfer equipment also makes it possible for a single worker to monitor an entire process, so companies can deploy workers more economically.

**Segregation prevention.** Segregation—the separation of a material's particles by size, shape, density, or other characteristic—is a major concern in pharmaceutical applications because it can threaten product quality. Manually transferring material in containers from machine to machine causes vibration, which promotes segregation. Vacuum transfer systems can minimize segregation by gently transferring pharmaceutical ingredients using mass flow, in which all particles move at the same velocity, so the particle distribution remains homogeneous.

**Increased throughput.** A vacuum conveyor also increases throughput by automating traditionally manual processes. A gelcap conveyor, for example, automatically transfers gelcaps, softgels, or tablets from inspection machines to packaging lines or delivers gelcaps to filling machines. These turnkey pneumatic systems can transfer 500 to 1,000 pounds per hour (approximately 2,500 units per minute), greatly increasing product throughput compared to manual transfer. Operating a gelcap conveyor requires a certain level of expertise, however, because gelcaps are delicate and manufacturing them can be an expensive process. Also, capsules are continuously impacting the receiving hopper wall during normal operation, so these systems can be somewhat noisy. Some new systems use a tangential hopper inlet to reduce this noise and protect the capsules from damage.

With respect to powder processes, a vacuum conveyor increases throughput by automatically refilling process equipment such as feeders while maintaining a dust-free processing environment, as opposed to manual refil, which increases the incidence of fugitive dust and worker safety issues.

**Decreased loading time.** Many types of pharmaceutical equipment, such as blenders, mixers, feeders, and reactors require either a mezzanine level for manual loading, a drum loader, or vacuum conveyor for automatic loading. While a
drum loader is more efficient than manual loading, only one drum can be loaded at a time, so material loading is still time-consuming. Also, some applications may require that you add multiple ingredients to the drums before loading the blender or reactor, which further slows the process.

A packaged pneumatic conveying system can help speed up the loading process for equipment capable of operating under a vacuum. The system includes the power source, filters, controls, and adapters, but rather than including a collection bin or hopper, the blender, mixer, or reactor acts as the primary receiving vessel. Such systems are configured specifically for each application using standard components and designed to minimize carryover, which is material that passes through the vessel and is captured by the filter between the vessel and the vacuum pump.

Both standing and suspended conveying systems are available. A standing unit is readily accessible for cleaning and can be equipped with casters, allowing a single unit to service more than one blender. In addition, once the blender is loaded and equalized, carryover releases into an airtight vessel allowing for reuse or safe disposal. With a suspended unit, once the blender is loaded and equalized, carryover automatically discharges back into the blender, eliminating the need to handle the material manually. Both conveying system types are easy to take apart without tools, so cleanup between batches and products takes less than an hour. Standard maintenance includes washing down equipment and changing out bags, filters, and hoses (when using different hoses for each material).

Prevention of material spills and mishandling. Manually scooping a tablet granulation into a tablet press can lead to spills or mishandling. A vacuum tablet press loader protects the formulation from contamination and spills, preventing waste. Vacuum tablet press loaders are fully enclosed, turnkey systems that automatically convey tablet granulations from drums or other containers or equipment to surge bins mounted above the tablet press. They are available for single- and dual-hopper tablet presses and their construction is USDA approved. A tube-hopper material receiver with vertical sides is located above each surge bin to minimize material hang-up, and a control panel and vacuum pump are located in an adjacent room. A single vacuum pump is sufficient to provide vacuum for all the material receivers above multiple tablet presses.

Reduced environmental impact. Vacuum technology can also help pharmaceutical processors comply with FDA and EPA wastewater collection guidelines. Wet central pharmaceutical vacuum systems are specifically designed to help pharmaceutical facilities comply with regulations that prohibit the disposal of liquids containing active pharmaceutical ingredients (APIs) and non-regulated pharmaceuticals and personal care products (PPCPs) into municipal wastewater sewer systems and municipal wastewater treatment plants (WWTPs).

This pharmaceutical liquid recovery system provides multiple hose connections located throughout a facility where washdown processes occur. The liquid generated from the washdown process (containing APIs and/or PPCPs) is vacuumed into a sanitary tubing network and then collected in a wet separator. For vertical tubing runs, special valves prevent the liquid from traveling backwards through the tubing when the system shuts down.

A filter made from a washable, corrosion-resistant filter media separates the contaminated liquid from the airstream, and an integral pump transfers the solution to an in-house treatment system. This type of industrial vacuum system typically includes a full controls package, liquid level sensors, sanitary construction, and protective secondary containment in the event of a contaminant release during maintenance or normal operation.

Pharmaceutical vacuum systems can also be used to prevent dry solids from entering drains and being carried to WWTPs, which can cost companies thousands of dollars per month in back charges. Pharmaceutical vacuum systems use techniques borrowed from other industries to separate the collected solids from the vacuum airstream for safe disposal and are constructed of stainless steel and designed to be explosion proof.

Regardless of the type of vacuum transfer equipment your pharmaceutical process requires, working with an experienced supplier will help ensure that you get the right equipment for the job and realize the benefits such a system can provide.

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